REMARKS

In the Office Action dated December 16, 2002, the Examiner has made the restriction requirement final. Therefore, Claims 1-22 are under consideration; Claims 23-29 are withdrawn from the consideration. The application has been objected to for certain informalities. Claim 11 has been objected to under 37 C.F.R. §1.75(c) as allegedly in improper form. Claims 1-22 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Claims 1-22 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. Claim 5 has been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1, 4, 6, 7, 10 and 11 have been rejected under 35 U.S.C. §102(a) as allegedly anticipated by Jiang et al. (1999) *Diabetes* 48:722-730 ("Jiang et al"). Claims 1, 6, 7, 12 and 17 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by either one of Kerr-Conte et al. (1996) *Diabetes* 1108-1114 (Kerr-Conte et al") or Dudek (1990) U.S. Patent No. 4,935,000 ("Dudek").

This Response addresses each of the Examiner's objections and rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The application has been objected to for certain informalities in the drawings. Applicants herewith submit corrected drawings in compliance with 37 C.F.R. §1.85. As such, the objection is overcome, and withdrawal thereof is respectfully requested.

Claim 11 has been objected to under 37 C.F.R. §1.75(c) as being in improper form. In response, Applicants have amended Claim 11 in compliance with 37 C.F.R. 1.75(c). As such, the objection to Claim 11 is overcome, and withdrawal thereof is respectfully requested.

Claims 1-22 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Specifically, the Examiner alleges that the molecules of the claims encompass a genus of any and all molecules capable of stimulating or otherwise facilitating the formation of colonies of pancreatic cells containing insulin-secreting cells. The Examiner contends that the four species disclosed by the present application are not representative of the widely divergent genus of any and all molecules capable of stimulating or otherwise facilitating the formation of colonies of pancreatic cells containing insulin-secreting cells. The Examiner further contends that the specification lacks descriptive support for derivatives, homologues and analogues of the claimed species.

In response, Applicants have amended independent Claims 1, 5 and 12 so that the molecule used in culturing the pancreatic epithelial cells is a bone morphogenic protein (BMP). Applicants have added Claims 30-32, wherein the pancreatic epithelial cells are cultured in the presence of a BMP and at least one of laminin-1 or laminin-1 containing extacellular matrix. Applicants have also canceled, without prejudice, Claims 6-7 and 16-22. Support for the amendment to Claims 1, 5 and 12, as well as for Claims 30-32 can be found throughout the specification. See, bridging paragraph of pages 14-15 for example and the original claims. Claims 1-22, as amended, and new Claims 30-32 no longer recite derivatives, homologues and analogues of a BMP molecule. Therefore, Claims 1-22, as amended, and new Claims 30-32 are described in the specification in such a way so as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. As such the rejection of Claims 1-22, as allegedly lacking written description, is overcome.

Claims 1-22 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. The Examiner concedes that the specification provides enablement for

methods of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells comprising culturing pancreatic cells in the presence of laminin-1, or in the presence of laminin-1 and BMP 6/6, BMP 7/7 and BMP 4/7. Specifically, the Examiner contends that the specification does not provide any method comprising culturing pancreatic cells in the absence of laminin-1 or in the presence of any and all functional derivatives, homologues, mimetics, analogues or agonists of BMP and laminin-1.

In response, as stated above, Applicants have amended independent Claims 1, 5 and 12. Applicants have also canceled Claims 6-7 and 16-22, without prejudice, and added Claims 30-32. Claims 1-22, as amended, and new Claims 30-32 do not recite functional derivatives, homologues, mimetics, analogues or agonists of a BMP molecule. In addition, Applicants submit that support for the methods of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells comprising culturing pancreatic cells in the absence of laminin-1, is found throughout the specification and particularly on page 14, lines 1-5 and 25-31. The specification also teaches assays for detecting formation of colonies containing insulin-secreting cells in Examples 18-20 (starting at page 38), for example. Applicants submit that given the present teaching those skilled in the art would be able to practice present method, by culturing pancreatic epithelial cells using BMP alone or in combination with laminin-1 or laminin-1-containing extracellular matrix, without undue experimentation. Therefore, Claims 1-22, as amended, added Claims 30-32 provide sufficient guidance to use the invention commensurate with the full scope of the claims, without engaging in undue experimentation. As such, the rejection of Claims 1-22, as allegedly lacking enabling support under 35 U.S.C. §112, first paragraph, is overcome, and withdrawal thereof is respectfully requested.

Claim 5 has been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Examiner alleges that the recitation "or both" is unclear. The Examiner suggests removal of the phrase will obviate the rejection. In response, the phrase has been deleted from Claim 5. Therefore, the rejection of Claim 5 is overcome.

Claims 1, 4, 6, 7, 10 and 11 have been rejected under 35 U.S.C. §102(a) as allegedly anticipated by Jiang et al.

The Examiner contends that Jiang et al. teach a method where pancreatic cells are cultured in the presence of laminin-1.

In response, Applicants respectfully direct the Examiner's attention to the amendment to the claims. According to the claimed methods, the pancreatic epithelial cells are cultured in the presence of at least a BMP. Jiang et al. do not teach the use of BMP to culture pancreatic epithelial cells. Therefore, Jiang et al. do not teach the claimed invention. Thus, the rejection of claims 1, 4, 6, 7, 10 and 11 under 35 U.S.C. §102(a) based on Jiang et al. is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1, 6, 7, 12 and 17 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by either one of Kerr-Conte et al. or Dudek.

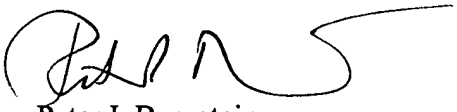
Specifically, the Examiner contends that Kerr-Conte et al. teach a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, stimulating or otherwise facilitating formation of cystic epithelial colonies containing insulin-secreting cells which method comprises culturing pancreatic cells in the presence of laminin-1-containing ECM for a time and under conditions sufficient for colonies to form comprising insulin secreting cells. The Examiner contends that Kerr-Conte et al. teach a method wherein the colonies of pancreatic cells containing insulin

secreting cells are cystic colonies. The Examiner also contends that Dudek teaches a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, which method comprises culturing pancreatic cells in the presence of laminin-1-containing ECM for a time and under conditions sufficient for colonies to form comprising insulin secreting cells. Further, Kerr-Conte et al. teaches a method wherein the colonies of pancreatic cells containing insulin-secreting cells are cystic colonies.

In response, Applicants have amended Claims 1 and 12. Applicants have also canceled Claims 6, 7 and 17, without prejudice. Applicants have added Claims 30-31 to further delineate Claim 1 and 5. According to the methods as presently claimed, pancreatic epithelial cells are cultured in the presence of at least a BMP. Neither of Kerr-Conte et al. or Dudek teach or disclose the use of a BMP in culturing pancreatic epithelial cells. As such the rejection of Claims 1, 6, 7, 12 and 17 as allegedly anticipated by either one of Kerr-Conte et al or Dudek, is overcome, and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, the present application is in condition for allowance which action is earnestly solicited.

Respectfully submitted,



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Enclosure: Substitute Drawings (Figs. 1-13)